

**REMARKS**

The above-identified Application has been carefully reviewed with the Office Action of July 8, 2008, the Examiner's comments, and the art references cited therein in mind. In response thereto, independent claims 1, 13 and 15 have been amended and the Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Initially, it is noted that the Request for Continued Examination was granted, the finality of the previous Office Action has been withdrawn and the Applicants' submission filed on 30 April 2008 has been entered.

Claims 1 and 3-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Siddiqui in view of Sparkes. Independent claims 1, 13 and 15 have been amended to more particularly point out the novelty of the present device and the patentability thereof over the cited prior art. Both of the prior art references have been discussed in detail during the prosecution of the present application. In short, Siddiqui is cited as a compression bone screw suitable for stabilizing a fractured bone. Siddiqui does not disclose that each of the screw head and distal portion includes at least one helical groove, firstly extending over the entire axial length of its threads and secondly being formed through each thread in such a manner to form tapping means. Sparkes is cited from the screw field as evidence for the use of a screw with at least one helical groove, firstly extending over the entire axial length of its threads and secondly being formed through each thread in such a manner to form tapping means. The Office's position concludes that it would have been obvious to modify the device of Siddiqui as taught by Sparkes to have exceptionally easy starting and insertion ability and to facilitate countersinking, and also reducing the danger of splitting the small bone fragments.

This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(A) Ascertaining the differences between the claimed invention and the prior art; and

- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United States Supreme Court decision in *KSR INTERNATIONAL CO. V. TELEFLEX INC. ET AL.* 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

In *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Id.*, at 17–18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for

combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

The Siddiqui reference can not be modified by Sparkes (or Jones as will be discussed hereinafter). Siddiqui makes this clear in the disclosure and teaches away from the Applicants' device thus conclusively demonstrating that it is indeed not obvious to make the modification proposed in the Office Action.

Siddiqui teaches, in Col. 4, lines 18-28 that

"Distal tip 31 of implant 1 includes cutting elements 33 configured to cut material as implant 1 is inserted. Alternatively, distal tip 31 may be configured with a smooth tip, such as a hemispherical tip.

Distal portion 7 preferably includes self-cutting channels or flutes 29 disposed proximal to distal tip 31 to prepare and tap the material for distal threads 11 during insertion. Thus, in the preferred embodiment, implant 1 is both self-drilling and self-tapping such that a pilot hole having a depth equal to or greater than the length of implant 1 is not required to insert the implant 1, as discussed below." (Emphasis added)

Thus, one presented with the "self-drilling and self-tapping" ability of Siddiqui could hardly be motivated to alter the design to include features from Sparkes (or Jones), i.e. to make it "more" self-drilling and self-tapping. However, even if the secondary references were consulted, the disclosures of Sparkes (and Jones) teach away from the pending claims.

On page 5 of the Office Action, in the "Response to Arguments" section, the Office takes the position that Sparkes screw exhibits a compression effect allowing said screw to compress bone fragments together as in the invention. This is not technically correct and goes beyond the objective teaching provided by Sparkes. The Office Action recites that in Col. 2, lines 57-62 of Sparkes that "the wood cuttings in the long spiral tend to be compressed and create an exceptional strong fastening quality of the screw in the wood. The spiral flute through the threads acts as a tap, cutting clean threads in the wood rather than compressing and splitting or weakening the material." (Emphasis added)

Thus, the teaching of Sparkes discloses merely that "the wood cuttings in the long spiral tend to be compressed. The Office Action then admits that "Sparkes does not want to compress or split or weaken the material around the area of the cut" and that "therefore Sparkes teaches of compressing the joined members". (Emphasis added) The statements contradict one another.

But Sparkes does not teach of compressing the joined members and in fact does not appear to even contemplate joining together two different members, but only contemplates

placing the screw in a single wood block 19. In other words, the issue of joining and compressing independent members is absent from Sparkes as it is not the purpose of the Sparkes invention. The only information provided by Sparkes is that the wood cuttings (and not the "joined members") which are inside the spiral are compressed. In contrast, the invention provides a compression screw used for coaptation of bone fragments in the step of compressing said bone fragments together by the insertion and turning of the screw. Such a compression effect is strictly impossible to obtain with Sparkes screw.

The Applicants maintain the argument that Sparkes is not analogous art. In addition to the above arguments that conclusively demonstrate that the combination of Siddiqui and Sparkes does not render obvious the presently pending claims, the amendments to claims 1, 13 and 15 are now believed to clarify the patentability of the Applicants' claimed novel device.

Claims 1 and 3-20 have also been rejected under 35 U.S.C. § 103(a) as being unpatentable over Siddiqui in view of Jones. The deficiencies of the Siddiqui reference in not teaching each of the screw head and the distal portion including at least one helical groove, firstly extending over the entire axial length of its threads, and secondly being formed through each thread in such a manner to form tapping means is combined with Jones which is cited for the provision of a screw with at least helical groove, firstly extending over the entire axial length of its threads, and secondly being formed through each thread in such a manner to form tapping means to permit the implant to cut its own threads in bone tissue and also to provide a place for packing bone fragment crumbs. (Office Action page 4).

This combination results from the use of hindsight knowledge of the invention for the following reasons: Jones teaches to implement a spiral flute which extends the full length of the screw (see Fig. 5). Therefore, implementing the flute of Jones in the screw of Siddiqui would lead to a screw which differs from the claimed device since its intermediate portion would not be smooth but would be equipped with a flute. In a compression screw, the smooth intermediate portion is the portion that is subject to the highest mechanical stresses. Hence, the skilled person would be deterred with taking into account the teaching of Jones, since it would lead to a mechanical weakening of the screw. Furthermore, even if the skilled person takes into account the teaching of Jones, he will only give a spiral shape to the straight flutes 29, 35 but he will not lengthen them in order to avoid a weakening of the screw. In other words, the combination of Siddiqui and Jones would lead to a screw with flutes as short as those of Siddiqui. Lastly, the primary purpose of the helical channel 53 made in Jones screw is to carry bone fragment crumbs deposited in the bone tissue hole prior to installation of implant 47 away from the distal end. This is stated in Col. 4, lines 24-28 of the Jones reference. In other words,

the helical channel is provided for clearing out the hole from the fragments and debris resulting from the cutting operations of the tubular saw 3 and the drill 5. In contrast, Siddiqui's screw is self-drilling (Col. 4, lines 26) so that a pilot hole is not required. Since a pilot hole is not required, and does not exist, there is of course no bone fragment crumbs to carry away. Therefore, the skilled person would have no objective reason to be interested in the helical channel of Jones, since Jones provides said helical channel for transporting bone fragment crumbs deposited in the bone tissue hole prior to installation of the implants.

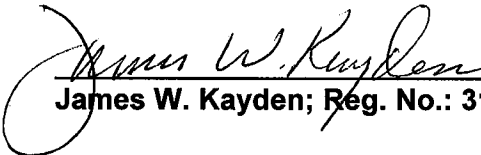
It is important to note that the presently claimed device is designed to compress bone fragments. While the Siddiqui device is designed to compress bone fragments, it has a design different from the Applicants' device. Had the Applicants' reviewed the Sparkes reference, it would have been dismissed as it does not compress the wood into which it is inserted. Similarly, knowing about the Siddiqui reference the Applicants would not turn to Jones for a solution to the deficiencies of Siddiqui provides a helical channel to carry material upwardly (as does Sparkes) in order to evenly distribute bone crumbs and encouraging the growth of bone tissue in and around the implant.

The reference to Maillefer has been reviewed; however, it should be noted that the purpose of Maillefer's helical groove is to give the tubular part of the stem of the pin a resiliency which allows its section to adapt itself perfectly to the section of the hole provided in the root of the tooth (Col. 2, lines 24-28). However, Siddiqui's screw is self drilling (Col. 4, line 26) so that no hole should be provided. Once again, only hindsight knowledge of the invention can lead the skilled person to consider Maillefer.

**CONCLUSION**

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,

  
James W. Kayden; Reg. No.: 31,532

**THOMAS, KAYDEN,  
HORSTEMEYER & RISLEY, L.L.P.**  
Suite 1500  
600 Galleria Parkway N.W.  
Atlanta, Georgia 30339  
(770) 933-9500